Proposed Registration Decision PRD2013-11

Metconazole

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Overview

Proposed Registration Decision for Metconazole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Metconazole Technical Fungicide and Tourney Fungicide, containing the technical grade active ingredient metconazole, to control several diseases on turfgrass on golf courses and sod farms.

Metconazole Technical Fungicide (Registration Number 29766) and Caramba Fungicide (Registration Number 29767) are conditionally registered in Canada. The detailed review for Metconazole Technical Fungicide and Caramba Fungicide can be found in Evaluation Report ERC2011-02, *Metconazole*. A portion of the data requirements identified for the conditional registration were also addressed in this application.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Metconazole Technical Fungicide and Tourney Fungicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on metconazole, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on metconazole, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Metconazole?

Metconazole is a triazole fungicide (demethylation-inhibiting fungicide) that inhibits sterol biosynthesis. The end-use product, Tourney Fungicide, contains 50.0% metconazole formulated as a water dispersible granule for use on turfgrass on golf courses and sod farms to control certain diseases.

Health Considerations

Can Approved Uses of Metconazole Affect Human Health?

Tourney Fungicide containing metconazole is unlikely to affect your health when used according to label directions.

Potential exposure to metconazole may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

The technical grade active ingredient, metconazole, was moderately toxic to rats and highly toxic to mice when given as a single oral dose. It was of low acute dermal toxicity to rats and rabbits and of low inhalation toxicity to rats. It was moderately irritating to the eyes and non-irritating to the skin of rabbits. It was not a potential skin sensitizer to guinea pigs. The signal words, "DANGER – POISON" and "EYE IRRITANT" have been included on the label in light of these findings. The end-use product, Tourney Fungicide, was found to be of slight oral acute toxicity and low dermal and inhalation acute toxicity in rats. It was minimally irritating to the eyes and non-irritating to skin of rabbits and not a dermal sensitizer in guinea pigs.

Health effects in animals given repeated daily doses of metconazole over longer periods of time were decreased body weights, effects in blood (regenerative anaemia) and microscopic changes to the liver, spleen and adrenal glands. There was no evidence that metconazole damaged genetic material. Skin tumours in male mice were observed following oral administration. There was no evidence of cancer in rats.

When metconazole was orally or dermally administered to pregnant rabbits, cranio-facial malformations were observed in fetuses. Limb-flexure malformations were observed in fetuses when metconazole was administered dermally to pregnant rabbits. These effects were observed at doses that were not toxic to the mother, indicating that the fetus is more sensitive to metconazole than the adult animal. Due to the serious nature of these endpoints, extra protective factors were applied during the risk assessment to further reduce the allowable level of human exposure to metconazole.

The risk assessment protects against the above effects by ensuring that the level of human exposure is well below the lowest dose at which the above effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and all infants less than one year old, the subpopulation that would ingest the most metconazole relative to body weight, are expected to be exposed to less than 56% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from metconazole is not of concern for all population subgroups. The lifetime cancer risk from the use of metconazole is considered acceptable.

Acute dietary (food and water) estimate for females 13–49 years old was less than 83% of the acute reference dose, and is not of health concern. For all other subpopulations, an acute reference dose was not established, therefore an acute dietary intake estimate is not required.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

No residue data are required to support the registration of metconazole for use in/on turfgrass on golf courses and sod farms in Canada. For the MRLs for this active ingredient on various crop commodities, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website.

Occupational Risks From Handling Tourney Fungicide

Occupational risks are not of concern when Tourney Fungicide is used according to the proposed label directions, which include protective measures.

Workers who mix, load or apply Tourney Fungicide, as well as workers re-entering freshly treated golf courses and sod farms, can come in direct contact with metconazole residues on the skin. Taking into consideration the approved personal protective equipment and engineered controls outlined in the Key Risk-Reduction Measures section below, the label statements, the number of applications and the expectation of the exposure period for handlers and workers, the non-cancer and cancer risks to these individuals are not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern when Tourney Fungicide is used according to label directions.

Adults and youth may be exposed to metconazole while golfing on treated courses. Based on the expected short-term duration of this activity, risk to golfers is not a concern. There were no cancer risks of concern.

Environmental Considerations

What Happens When Metconazole Is Introduced Into the Environment?

Metconazole is toxic to non-target terrestrial plants, birds, small wild mammals and aquatic organisms. It is persistent in soil and aquatic sediment; however, it is not persistent in water. Metconazole is a potential leacher and may reach groundwater. Label instructions, including spray buffer zones, are required.

Metconazole enters the environment when used as a fungicide on agricultural crops and on turfgrass. Metconazole is moderately persistent to persistent in the terrestrial environment. It is relatively stable to hydrolysis and phototransformation, undergoing minor biotransformation in both soil and water. Despite its high soil adsorption, metconazole has the potential to leach into groundwater due to its solubility in water and persistence in soil. Based on its low volatility (low vapour pressure and Henry's law constant), metconazole residues are not expected in the air, nor is long-range aerial transport expected. Specific instructions to mitigate carryover, groundwater contamination and runoff into aquatic habitats are provided on the end-use product label.

Metconazole presents a negligible risk to terrestrial invertebrates including earthworms and honeybees, freshwater invertebrates including daphnids, juvenile stages of freshwater fish, freshwater algae, marine fish and marine algae. However, it may adversely affect non-target terrestrial plants, birds, small wild mammals, amphibians, early life stages of freshwater fish, freshwater aquatic vascular plants and marine invertebrates, including mysid shrimps. Therefore, toxicity statements for non-target terrestrial plants, birds, mammals, and aquatic organisms are specified on the product label. Spray buffer zones are also required to protect terrestrial, freshwater and estuarine/marine habitats adjacent to areas treated with metconazole fungicide.

Value Considerations

What Is the Value of Tourney Fungicide?

As a new fungicide active ingredient for use on turfgrass, Tourney Fungicide contributes to integrated pest management on golf courses and sod farms.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Tourney Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Tourney Fungicide on the skin or through inhalation of spray mists, anyone mixing, loading and applying must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves when handling up to 18.5 kg of Tourney Fungicide during groundboom application or when handling up to 2.1 kg of Tourney Fungicide during low pressure turf gun application. When handling more than 18.5 kg of Tourney Fungicide during groundboom application, mixer/loader/applicators must wear cotton coveralls over a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves

and must apply using a closed cab tractor. When handling more than 2.1 kg of Tourney Fungicide during low pressure turf gun application, workers must wear cotton coveralls over a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves. The label also requires that workers do not enter treated golf courses and sod farms for 24 hours after application for transplanting, planting and slab harvesting activities. For other activities, the label requires that workers do not enter treated areas until sprays have dried.

Environment

For field sprayer application on turfgrass, spray buffer zones up to 5 metres in width are required to protect sensitive aquatic and terrestrial habitats from spray drift of Tourney Fungicide.

Next Steps

Before making a final registration decision on metconazole, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

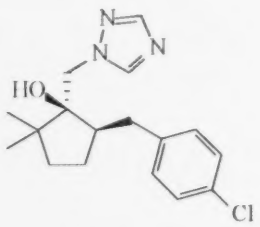
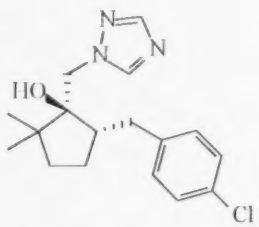
When the PMRA makes its registration decision, it will publish a Registration Decision on metconazole (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Metconazole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Metconazole
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(1*RS*,5*RS*;1*RS*,5*SR*)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol
2. Chemical Abstracts Service (CAS)	5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol
CAS number	125116-23-6
Molecular formula	$C_{17}H_{22}ClN_3O$
Molecular weight	319.83
Structural formula	 cis-metconazole (1RS,5RS)  trans-metconazole (1RS,5SR)
Purity of the active ingredient	97.0% nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Metconazole Technical

Property	Result
Colour and physical state	White solid
Odour	Odourless
Melting range	100.0–108.4°C
Boiling point or range	N/A
Density	1.14
Vapour pressure at 20°C	Analyte — Vapour pressure (Pa) AI — $< 1.23 \times 10^{-5}$ cis-isomer — $< 1.04 \times 10^{-5}$ trans-isomer — $< 1.96 \times 10^{-6}$
Henry's law constant at 20°C	2.08×10^{-9} atm/m^3/mol
Ultraviolet (UV)-visible spectrum	λ_{max} = 221.4 nm
Solubility in water at 20°C	Analyte — Solubility (µg/mL) AI — 30.4 cis-isomer — 17.1 trans-isomer — 13.6
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — AI — cis — trans dichloromethane — 481 — 343 — 141 methanol — 403 — 291 — 117 acetone — 363 — 251 — 117 ethyl acetate — 260 — 173 — 90 2-propanol — 132 — 86.6 — 46.7 toluene — 103 — 66.2 — 38 hexane — 1.4 — 0.929 — 0.483
n Octanol-water partition coefficient (K_{ow})	K_{ow} — log K_{ow} AI — 7090 ± 989 — 3.85 cis — 7150 ± 803 — 3.85 trans — 6800 ± 1700 — 3.8
Dissociation constant (pK_a)	pK_{a1} = 11.38 ± 0.03 pK_{a2} = 1.06 ± 0.03

Stability (temperature, metal)	The product was found to be stable in the presence of metals in both their natural state (aluminum and iron) and their ionic form (aluminum acetate and iron acetate) at normal and elevated temperature (25 ± 2°C and 54 ± 2°C, respectively).

End-Use Product—Tourney Fungicide

Property	Result
Colour	Beige
Odour	N/A
Physical state	Granules
Formulation type	WG
Guarantee	50% nominal
Container material and description	Plastic jugs
Density	0.52–0.53 g/cm^3
pH of 1% dispersion in water	8.4
Oxidizing or reducing action	The product does not react with granular zinc (a reducing agent). The product generates heat on contact with aqueous potassium permanganate (an oxidizing agent)
Storage stability	The product is stable when stored in commercial packaging under warehouse conditions.
Corrosion characteristics	No signs of corrosion during 12 months storage in commercial containers.
Explodability	The product has no explosive properties.

1.3 Directions for Use

Tourney Fungicide is for use on high value turfgrasses grown on golf courses and sod farms for control of anthracnose basal rot and foliar blight, brown patch, dollar spot, summer patch, waitea patch, grey snow mould and pink snow mould. The product is applied once at rates ranging from 8.4–11.2 g/100 m^2 for summer diseases. For pink and grey snow moulds, Tourney Fungicide is applied at 11.2 g/100 m^2 in combination with 250 g chlorothalonil/100 m^2.

Tourney Fungicide is applied preventatively using ground application equipment at water volumes ranging from 8 to 16 L/ha. For control of crown or root diseases, Tourney can be watered in after application. Higher rates are to be used when conditions are optimal for disease development, when there is a history of severe disease pressure, or when the product is applied curatively.

1.4 Mode of Action

Metconazole is a broad-spectrum triazole fungicide that works by inhibiting demethylation and other processes in sterol biosynthesis. Metconazole has no effect on fungal spore germination; however, it interferes with other early developmental processes in the life cycle of certain fungi. Although metconazole cannot prevent spore germination, it prevents spore formation and inhibits mycelial growth.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Metconazole Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

The methods previously provided for residue analysis in soil, sediment and water were assessed to be acceptable for data generation and enforcement purposes.

Please refer to Evaluation Report ERC2011-02, *Metconazole* for residue analytical methods for data generation and enforcement purposes.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for metconazole was previously conducted in 2007 and published in ERC2011-02. The database is complete, consisting of the full array of toxicity currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to metconazole.

The registered technical grade active ingredient is comprised of the cis and trans isomers of metconazole at a minimum of 80:20 (cis:trans). The majority of the studies in the database were performed with this isomeric ratio. For the rabbit oral developmental toxicity studies, three supplementary studies were performed on the cis, (-)cis and trans isomers which confirmed the increased developmental toxicity potential of the cis isomer.

From the information available for the 2007 review, the primary target organs were the liver, adrenals and reproductive organs, all showing signs of durational effects, as well as signs of irritation and regenerative anaemia. In dogs, the eye was also a target. Male mice exhibited a dose-related increase in skin sarcomas at all doses tested. There were liver tumours at the highest doses tested in male and female mice; however, an acceptable mode of action (MOA) was provided by the applicant to support a threshold approach to risk assessment. There was no evidence of genotoxicity, or cancer in rats. When administered to pregnant rabbits, craniofacial malformations were observed at doses that did not elicit maternal toxicity, and in rats, spinal malformations were only observed at maternally toxic doses.

This updated toxicology review of metconazole was conducted to assess a major new use (turf). In the 2007 review, there was sufficient information to complete the risk assessment; however, it was communicated to the applicant that the risk assessment may be further refined with scientifically valid MOA information and relevant historical controls for the skin tumours and a rabbit dermal developmental toxicity study to refine the dermal occupational endpoints. In this application, the applicant submitted weight of evidence information on the non-skin sensitizing potential of the active, an immunotoxicity study in rats, MOA and historical control information on skin sarcomas in group-housed mice and a rabbit dermal developmental toxicity study. The following is an update of the hazard assessment following evaluation of the new information.

Acute studies indicated that metconazole was of high oral toxicity to mice, moderate oral toxicity to rats, low dermal toxicity to rats, low dermal toxicity to rabbits and low inhalation toxicity to rats. Metconazole was moderately irritating to the eyes of rabbits. It was not irritating to the skin of rabbits and was not a potential skin sensitizer in guinea pigs.

In a 29-day immunotoxicity study in rats, there were no signs of immunotoxic potential, nor were there signs of immunotoxicity in the rest of the database.

In the mouse 91-week study, there were neoplasms in the liver and skin. In the liver, incidence of adenomas and carcinomas were increased above concurrent controls at the highest dose tested and skin sarcomas were increased above concurrent controls at all doses tested. The skin sarcomas occurred at a frequency of 0, 3.9, 5.9 and 9.8% of the animals at doses of 0, 30, 300 and 1000 ppm respectively. This exceeded the publically available historical control values of 1.5–2.0% in all dose groups supplied by the company that supplied the animals used in the study.

The applicant submitted an MOA hypothesising that group-housed male mice were more likely to fight, leading to sores and then to a random occurrence of fibromas and sarcomas. However, the lab-specific historical control data provided on skin sarcomas demonstrated that the incidence at the high dose was outside the historical range for group-housed animals and the clinical observation data provided did not support the applicant's proposal that animals with tumours had prolonged sores. Further, no scientific data or references were provided to support the link between prolonged skin sores and sarcomas, a tumour of the deeper layer of the epidermis. The detailed histopathological descriptions did support including the fibroma observed in one control animal in the calculation of the q_1* and the linear low dose extrapolation was revised to take this finding into account.

In the rabbit dermal developmental toxicity study, there was evidence of maternal toxicity at the high dose with decreased body weight gains and food consumption, and increased total and late resorptions and postimplantation loss. At maternally non-toxic levels, there were craniofacial and limb-flexure malformations, indicating sensitivity of the young. While occurring at a low incidence, the craniofacial malformations were of the same types as those seen in the rabbit oral developmental toxicity studies and were determined to be treatment-related. At maternally toxic dose levels, fetal body weights were decreased.

Results of the immunotoxicity and rabbit dermal developmental toxicity studies conducted on laboratory animals are summarized in Appendix I, Table 1. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 2.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the Pest Management Regulatory Agency (PMRA). Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Incidents were searched and reviewed for the active ingredient metconazole. As of 22 February 2013, the PMRA had received six incident reports: two human incidents; one incident involving human and environmental effects; one packaging failure incident; and two scientific studies.

The symptoms in two of the human incidents were considered to be possibly related to the reported pesticide exposure. The effects noted in these reports were eye irritation, pain, itchy skin, hives, erythema, rash and nausea. The third human incident was considered unlikely to be related to the reported pesticide exposure. These human incident reports were considered in this evaluation and did not affect the risk assessment.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for metconazole. The database contains the full complement of required studies including sufficient information to determine pre- and post-natal toxicity. There was a 2-generation oral reproductive toxicity study along with a supplementary oral study investigating hormonal changes in the rat during gestation. There were preliminary and definitive rat oral developmental toxicity studies. The rabbit developmental toxicity studies

consisted of one preliminary oral study[5] and two definitive oral studies, as well as a dermal developmental toxicity study on the cis:trans isomer mixture. There were also two oral studies on the cis isomer and an oral study of the cis, (-)cis and trans isomers. The cis, (-)cis and trans studies were not representative of the material intended for commerce and were not used in the risk assessment.

With respect to potential pre- and post-natal toxicity, effects were observed in all studies. In the rat reproductive toxicity study, there were decreases in offspring survival and live birth and viability indices. Sensitivity of the young was identified in the rabbit oral developmental toxicity study (ERC 2011-02) and the rabbit dermal developmental toxicity study, in which serious effects were noted in the fetuses (i.e., craniofacial and limb-flexure malformations) at a maternally non-toxic dose. There were increases in spinal column malformations in the rat oral developmental toxicity study. The fetal effects in rats occurred at maternally toxic doses and at doses greater than the doses producing malformations in rabbits.

Although craniofacial malformations did not occur in a second rabbit oral developmental toxicity study, craniofacial malformations have been observed with other conazole pesticides and the malformations in both the initial oral study as well as the dermal study were considered treatment-related. This information was taken into account in determining the appropriate factors in the risk assessment.

Overall, given the serious nature of the endpoint (malformations occurring in the absence of maternal toxicity), the PCPA factor was retained at 10-fold when the developmental endpoint was used for the risk assessment. Otherwise, the PCPA factor was reduced to 1-fold.

3.2 Acute Reference Dose (ARfD)

There has been no change in the ARfD from that reported in Evaluation Report ERC2011-02-*Metconazole*. Please refer to Appendix I, Table 3.

3.3 Acceptable Daily Intake (ADI)

There has been no change in the ADI from those reported in Evaluation Report ERC2011-02-*Metconazole*. Please refer to Appendix I, Table 3.

Cancer Assessment

In the absence of sufficient mode of action data on the skin sarcomas in male mice to support a threshold approach to the cancer risk assessment, a linear low dose extrapolation approach (q_1*) was used for metconazole. Unit risks for metconazole, denoted by q_1* (representing the upper 95% confidence limit on the slope of the dose-response curve in the low-dose region), were

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[5] Evaluation Report ERC2011-02 contains a typographical error with regards to the PMRA numbers of the following studies: the study listed in the evaluation report as PMRA #145647 should be PMRA #1405647; PMRA #145464 should be 1405464 and PMRA #145645 should be PMRA #1405645.

calculated on the basis of the bioassay data from the 91-week carcinogenicity study in mice. A revised adjusted q_1^* value of 8.0×10^{-3} $(mg/kg\ bw/d)^{-1}$ was derived in male mice based on the combined incidence of skin fibromas/sarcomas.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Short- and Intermediate-term Dermal

The no observed adverse effect level (NOAEL) of 30 mg/kg bw/d from the rabbit dermal developmental toxicity study is considered the most appropriate endpoint for short and intermediate-term dermal risk assessment. The NOAEL is based on craniofacial and limb flexure malformation in fetuses at the next higher dose level. The study was conducted by the relevant route and measured endpoints of concern in the database not assessed in the 21-day dermal study. The worker population could include females of child bearing age (13–49) and therefore these endpoints were considered appropriate for the occupational risk assessment. For this reason, the target margin of exposure (MOE) is 1000, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as the additional 10-fold factor to protect the unborn children of exposed female workers for the reasons outlined in the PCPA section.

Short- and Intermediate-term Inhalation

The NOAEL of 2 mg/kg bw/d from the rabbit oral developmental toxicity study is considered the most appropriate endpoint for short and intermediate-term inhalation risk assessment. The NOAEL is based on the observation of craniofacial malformations in fetuses at the next higher dose level. The worker population could include females of child bearing age (13–49) and therefore these endpoints were considered appropriate for the occupational risk assessment. For this reason, the target MOE is 1000, accounting for standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as the additional 10-fold factor to protect the unborn children of exposed female workers for the reasons outlined in the PCPA section.

Occupational exposure to metconazole is characterized as short-term and is predominantly by the dermal and inhalation route. Exposure when golfing in treated golf courses is characterized as short-term and is predominately by the dermal route.

3.4.1.1 Dermal Absorption

The dermal absorption of metconazole is described in detail in ERC2011-02. The dermal absorption of 21% from an in vivo rat dermal absorption study was considered most appropriate for risk assessment purposes. The dermal absorption value of 21% was used in the cancer risk assessment. However, the dermal absorption value was not applied in the non-cancer risk assessment, since the dermal toxicological endpoint is based on a dermal developmental study.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to metconazole during mixing, loading and application. Exposure to golf course and sod farm workers mixing, loading and applying Tourney Fungicide is expected to be short-term in duration and to occur primarily by the dermal and inhalation routes. Mixer/loader/applicator exposure estimates were derived from applying metconazole on golf courses and sod farms at the maximum rate using groundboom and low pressure turf gun.

The exposure estimates were based on mixer/loader/applicators with the following personal protective equipment and engineering controls:

- When handling 18.5 kg of Tourney Fungicide or less for groundboom applications OR when handling 2.1 kg of Tourney Fungicide or less for turf gun applications,
    - Wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks
- When handling more than 18.5 kg Tourney Fungicide for groundboom applications OR when handling more than 2.1 kg of Tourney Fungicide for turf gun applications,
    - Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks
    - Use closed cab tractor for groundboom application.

As chemical-specific data for assessing human exposures were not submitted, dermal and inhalation exposures for workers involved with groundboom application were estimated using the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. Dermal and inhalation exposures for workers involved with low pressure hand gun application were estimated using a study from the Outdoor Residential Exposure Task Force (ORETF).

For the non-cancer mixer/loader/applicator risk assessment, exposure was estimated by coupling the dermal unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the inhalation unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (NOAELs) to obtain the MOE; the target MOE is 1000. Table 3.4.2.1.1 presents the PHED and ORETF unit exposure values used. Table 3.4.2.1.2 presents the estimates of exposure and non-cancer risk for Tourney Fungicide. Calculated MOEs are above the target MOE of 1000 for workers who wear the personal protective equipment stated on the product labels.

Table 3.4.2.1.1. PHED and ORETF unit exposure estimates for mixer/loader/applicators while handling Tourney Fungicide

ML, A, or MLA	Occupational scenario		Clothing scenario	PHED/ORETF unit exposures (µg/kg a.i. handled)		
				Dermal	Inhalation	Combined*
ML	A	DF, open ML	Single layer with CR gloves	163.77	1.02	35.41
ML	B	DF, open ML	Cotton coveralls over single layer with CR gloves	91.94	1.02	20.33
A	C	Groundboom, open cab	Single layer	32.98	0.96	7.89
A	D	Groundboom, closed cab	Cotton coveralls over single layer with CR gloves	4.42	0.06	0.99
MLA	E	Low pressure turf gun	Single layer with CR gloves	1290	47.8	318.70
MLA	F	Low pressure turf gun	Cotton coveralls over single layer with CR gloves	433	47.8	138.73
MLA	A+C	Open ML, open cab GB	Single layer with CR gloves	196.75	1.98	43.30
MLA	B+D	Open ML, closed cab GB	Cotton coveralls over single layer with CR gloves	96.36	1.08	21.32

ML = mixing/loading, A = applying, MLA = mixing/loading and applying, DF = dry flowable, GB = groundboom, CR = chemical-resistant

* Combined PHED unit exposure = (Dermal unit exposure × 21% dermal absorption) + (Inhalation unit exposure × 100% inhalation exposure)

NOTE: The separate dermal and inhalation PHED unit exposures are used in the non-cancer risk assessment, since the dermal and inhalation NOAELs are different.

The combined PHED unit exposures are used in the cancer risk assessment.

Table 3.4.2.1.2. Chemical handler non-cancer risk assessment for Tourney Fungicide

Occupational/ Clothing scenario		PHED/ORETF unit exposure (µg/kg a.i. handled)[1]		ATPD[2] (ha/day)	Exposure[3] (mg/kg bw/day)		Calculated MOE[4]		
		Dermal	Inhalation		Dermal	Inhalation	Dermal	Inhalation	Combined
Golf course workers using groundboom									
A+C	Single layer and CR gloves, open cab	196.75	1.98	16	0.0252	0.00025	1191	7891	1035
Sod farm workers using groundboom									
A+C	Single layer and CR gloves, open cab	196.75	1.98	30	0.0472	0.00048	635	4209	**552**
A+C	Single layer and CR gloves, open cab	196.75	1.98	16.5*	0.0260	0.00026	1154	7644	1003
B+D	Cotton coveralls over single layer and CR gloves, closed cab	96.36	1.08	30	0.0231	0.00026	1297	7716	1111

Occupational/ Clothing scenario		PHED/ORETF unit exposure (µg/kg a.i. handled)[1]		ATPD[2] (ha/day)	Exposure[3] (mg/kg bw/day)		Calculated MOE[4]		
		Dermal	Inhalation		Dermal	Inhalation	Dermal	Inhalation	Combined
Golf course and sod farm workers using low pressure hand gun									
E	Single layer and CR gloves	1290	47.8	2	0.0206	0.00076	1453	2615	**934**
E	Single layer and CR gloves	1290	47.8	1.875†	0.0194	0.00072	1550	2789	*997*
F	Cotton coveralls over single layer and CR gloves.	433	47.8	2	0.0069	0.00076	4330	2615	1630

Calculated MOEs in bold are below the target MOE of 1000.

Calculated MOE in italics is deemed acceptable, considering the conservatisms of the risk assessment.

CR = chemical-resistant

[1] PHED/ORETF unit exposures from Table 3.4.2.1.1

[2] Default Area Treated per day values for turf

[3] Exposure = (PHED/ORETF unit exposure × ATPD × 0.560 kg a.i./ha) / (70 kg bw x 1000 µg/mg)

[4] Dermal MOE: based on NOAEL = 30 mg/kg bw/day, target MOE = 1000.
Inhalation MOE: based on NOAEL= 2 mg/kg bw/day, target MOE = 1000
Combined MOE = 1/[(1/dermal MOE) + (1/inhalation MOE)]; target MOE = 1000

* Based on a 18.5 kg product per day restriction

† Based on a 2.1 kg product per day restriction

For the cancer mixer/loader/applicator risk assessment, exposure was estimated by coupling the combined unit exposure values (dermal unit exposure and inhalation unit exposure) from Table 3.4.2.1.1 with the amount of product handled per day. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight to be expressed as average daily dose (ADD).

To calculate the potential lifetime exposure of golf course and sod farm workers handling metconazole, mixer/loader/applicator exposures were amortized over an individual's lifetime. This was expressed as the lifetime average daily dose (LADD), which takes into account multiple exposure scenarios and the frequency of exposure scenarios throughout the individual's lifetime. To calculate the LADD, the treatment frequency was 1 day per year, which is the maximum number of applications per year for Tourney Fungicide. Mixer/loader/applicators could potentially have a working tenure of 40 years and life expectancy was assumed to be 75 years. Cancer risk was estimated by multiplying the LADD by the q_1* value of 8.00×10^{-3} $(mg/kg\ bw/day)^{-1}$. Table 3.4.2.1.3 presents the estimates of exposure and cancer risk for Tourney Fungicide. Calculated cancer risk estimates are below 1×10^{-5}. Therefore, from both non-cancer and cancer risk mixer/loader/applicator assessments, risks are not of concern, provided that workers wear the personal protective equipment stated on the product label.

Table 3.4.2.1.3. Chemical handler cancer risk assessment for Tourney Fungicide

Exposure scenario	Combined PHED unit exposure (µg/kg a.i. handled)[1]	Rate (kg a.i./ha)	ATPD (ha/day)[2]	ADD (mg/kg bw/day)[3]	Days of exposure (days/yr)	LADD (mg/kg bw/day)[4]	Cancer risk[5]
Golf course workers using groundboom							
Single layer and CR gloves, open cab	43.30	0.56	16	0.0055	1	8.10E-06	6E-08
Sod farm workers using groundboom							
Single layer and CR gloves, open cab	43.30	0.56	16.5*	0.0057	1	8.35E-06	7E-08
Cotton coveralls over single layer and CR gloves, closed cab	21.32	0.56	30	0.0051	1	7.48E-06	6E-08
Golf course and sod farm workers using low pressure hand gun							
Single layer and CR gloves	318.70	0.56	1.875†	0.0048	1	6.99E-06	6E-08
Cotton coveralls over single layer and CR gloves	138.73	0.56	2	0.0022	1	3.24E-06	3E-08

[1] PHED/ORETF combined unit exposures from Table 3.4.2.1.1

[2] Default Area Treated per day values for turf

[3] ADD = Average daily dose = (PHED unit exposure × ATPD × Rate) / (70 kg bw × 1000 µg/mg)

[4] LADD = Lifetime average daily dose
= (ADD × Days of exposure × 40 years working duration) / (365 days/year × 75 years life expectancy)

[5] Cancer risk = LADD × q_1*; q_1* = 8.00×10^{-3}

* Based on a 18.5 kg product per day restriction

† Based on a 2.1 kg product per day restriction

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering golf courses and sod farms treated with Tourney Fungicide when conducting various activities. The duration of exposure is considered to be short-term for all re-entry activities. The primary route of exposure for workers re-entering treated areas would be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route, since metconazole is relatively non-volatile (1.23×10^{-5} Pa) and as such, an inhalation risk assessment was not required.

Postapplication risk assessments were conducted with the maximum rate of Tourney Fungicide. Dermal exposure to workers entering treated areas was estimated by coupling transferable turf residue (TTR) values with activity-specific transfer coefficients and an exposure duration of 8 hours per day.

Chemical-specific TTR data were submitted. The two submitted TTR studies were designed to determine transferable residues of metconazole from turf treated with a flowable formulation containing 21% of a mixture of 85% *cis*- and 15% *trans*-metconazole at a target of 672 g a.i./ha. The product was applied twice, 14 to 15 days apart. The first study was conducted in one location in Grand Rapids, Ottawa County, Michigan, where the product was applied using a tractor mounted platform boom sprayer. The second study was conducted in one location in

Athens, Clarke County, Georgia, where the product was applied using a tractor mounted, compressed air driven boom sprayer. In both studies, transferable residues were measured using the modified California roller method for TTR. Triplicate TTR samples were collected at –1 (pre-treat), 0 and 13 days after the first application, and at 0, 1, 2, 3, 5, 7, 10, 14, 21, and 28 days after the last application (DALA). Samples at 35 DALA were also taken in the Georgia study.

In the study conducted in Michigan, the maximum average total metconazole TTR occurred on one DALA at 0.090 µg/cm^2, which represents 1.3% of the original application rate. Total metconazole residues had declined to or less than the limit of detection (LOD; 0.001 µg/cm^2) by 5 DALA. Assuming first-order dissipation kinetics, estimated half-life values were 0.781 days (R^2 = 0.614) for total metconazole, 0.699 days (R^2 = 0.619) for *cis*-metconazole, and 0.558 days (R^2 = 0.533) for *trans*-metconazole. Limitations of the study include the lack of field fortifications (though laboratory recoveries were acceptable) and the excessive rainfall for four consecutive days after the second application.

In the study conducted in Georgia, the maximum average total metconazole TTR occurred immediately after the first application at 0.026 µg/cm^2, which represents 0.39% of the original application rate. Total metconazole residues had declined to or less than the LOD (0.001 µg/cm^2) by 5 DALA. Assuming first-order dissipation, estimated half-life values were 1.03 days (R^2 = 0.894) for total metconazole, 0.877 days (R^2 = 0.925) for *cis*-metconazole, and 0.712 days (R^2 = 0.927) for *trans*-metconazole. The dissipation curves for total, *cis*- and *trans*- metconazole from Georgia all have R^2 values higher than 0.85, which indicates that there is adequate correlation between the residue levels and time to describe the chemical dissipation using a linear equation. Predicted daily dissipation values were 49.1% for total metconazole residues, 54.6% for *cis*-metconazole residues and 62.2% for *trans*-metconazole residues.

The two TTR studies were considered acceptable for risk assessment purposes. The application method and use pattern of the two studies are relevant to the Canadian use of metconazole on turfgrass. The peak TTR value for total metconazole residues from the Michigan study (1.3% of the application rate) was used in the postapplication risk assessment for Tourney Fungicide, since the peak TTR value is more conservative than that from the Georgia study. However, the dissipation data from the Michigan data are less reliable because of their lack of field fortifications, the excessive rainfall that the site received and the poor R^2 of the dissipation curve. As such, the predicted dissipation from the Georgia site (49.1% per day for total metconazole residues) was used in the postapplication risk assessment.

For postapplication non-cancer risk, the dermal exposure estimates were compared to the toxicological endpoint (NOAEL = 30 mg/kg bw/day) to obtain the MOE; the target MOE is 1000. Table 3.4.2.2.1 presents the calculated MOEs on the day of application and the resulting restricted-entry intervals (REIs) based on non-cancer risk only.

Table 3.4.2.2.1. Postapplication exposure and non-cancer risk estimates on the day of application for golf courses and sod farms treated with Tourney Fungicide

Re-entry activity	Peak TTR ($\mu g/cm^2$)[1]	Transfer Coefficient (cm^2/hr)[2]	Dermal Exposure (mg/kg bw/day)[3]	MOE[4]	REI
Golf course workers and sod farm workers					
Transplanting and planting (and slab harvesting for sod farm workers)	0.0728	6700	0.0557	538	1 day
	0.0371 (on Day 1)		0.0284	1057	
Mowing, watering, and irrigation repair (and cup changing and miscellaneous grooming for golf course workers)	0.0728	3500	0.0291	1030	Until sprays have dried
Aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	0.0728	1000	0.0083	3606	

[1] Calculated based on TTR values from submitted studies (1.3% TTR on day of application and 49.1% dissipation per day)
[2] Transfer coefficients from the Agricultural Reentry Task Force (ARTF)
[3] Dermal Exposure = (Peak TTR × Transfer Coefficient × 8 hours/day)/(70 kg bw × 1000 µg/mg)
[4] Based on NOAEL= 30 mg/kg bw/day, target MOE = 1000

To assess postapplication cancer risk, the number of days of postapplication exposure was assumed to be 20 days for transplanting, planting and slab harvesting (as workers conduct these activities 5 days per week) and 14 days for other re-entry activities (as workers conduct these activities every two days). Exposure was estimated using the time-weighted average (TWA) TTR, which was calculated over 30 days postapplication using the TTR values from the submitted studies (1.3% of the application rate transferable on the day of application and 49.1% daily dissipation). The same activity-specific transfer coefficients and exposure duration were used in the non-cancer and cancer risk assessments.

To calculate the potential lifetime exposure of re-entry workers to metconazole residues as a consequence of postapplication activities, exposures were amortized over an individual's lifetime. This was expressed as the LADD, which takes into account the frequency of exposure throughout the individual's lifetime. Workers were assumed to have a working tenure of 40 years and life expectancy of 75 years. The cancer risk was estimated by multiplying the LADD by the q_1^* value of 8×10^{-3} $(mg/kg\ bw/day)^{-1}$.

The postapplication cancer risk assessment is presented in Table 3.4.2.2.2. Calculated cancer risk estimates for all scenarios are below 1×10^{-5}. As such, taking into account both the non-cancer and cancer postapplication risk assessment, an REI of 1 day is adequate for transplanting, planting and slab harvesting treated areas. For other activities, workers may re-enter after sprays have dried.

Table 3.4.2.2.2. Postapplication exposure and cancer risk estimates for golf courses and sod farms treated with Tourney Fungicide

Re-entry activity	TWA TTR ($\mu g/cm^2$)[1]	TC (cm^2/hr)[2]	ADD (mg/kg bw/day)[3]	Days of exposure per year	LADD (mg/kg bw/day)[4]	Cancer risk[5]
Golf course workers and sod farm workers						
Transplanting and planting (and slab harvesting for sod farm workers)	0.00260 (after 1-day REI)	6700	4.18E-04	20	1.22E-05	1E-07
Mowing, watering, and irrigation repair (and cup changing and miscellaneous grooming for golf course workers)	0.00494	3500	4.15E-04	14	8.49E-06	7E-08
Aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	0.00494	1000	1.19E-04	14	2.43E-06	2E-08

[1] TWA TTR = 30-day time-weighted average TTR, after the required REI from the non-cancer risk assessment
[2] TC = Transfer coefficients from the Agricultural Reentry Task Force (ARTF)
[3] ADD = average daily dose
= (TWA TTR × TC × 8 hours/day × 21% dermal absorption)/(70 kg bw × 1000 µg/mg)
[4] LADD = lifetime average daily dose
= (ADD × Days of exposure/yr × 40 years working duration) / (365 days/year × 75 years life expectancy)
[5] Cancer risk = LADD × q_1*; q_1* = 8.00×10^{-3}

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Tourney Fungicide is not a domestic product; therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

There is potential for postapplication exposure to the general population entering areas treated with Tourney Fungicide. Although Tourney Fungicide is not for use on residential turf, it is used on golf courses where youth and adults may enter. The duration of exposure is considered to be short-term for golfing. The primary route of exposure for these individuals would be through the dermal route. Metconazole is considered non-volatile and it is not an inhalation concern for postapplication exposure.

For the non-cancer risk assessment, dermal exposure was assessed for females 13–49 years, since the non-cancer toxicological endpoint is based on developmental effects in the fetus in the absence of maternal toxicity. The risk assessment for females 13–49 years will cover off risk from golfing for other populations, since the short- to intermediate-term dermal endpoint established for females 13–49 years was considered protective for other populations. Dermal exposure to golfers is estimated by coupling the TTR value with the transfer coefficient for golfing and the exposure duration of 4 hours per day. The TTR value on the day of application was calculated using 1.3% of the application rate transferable on the day of application, based on

the Michigan TTR study. Non-cancer risk was calculated using the short- to intermediate-term dermal endpoint (NOAEL = 30 mg/kg bw/day; target MOE = 1000). Table 3.4.3.2.1 presents the calculated MOE on the day of application, which is above the target MOE of 1000.

Table 3.4.3.2.1. Postapplication exposure and non-cancer risk estimates for golfers re-entering golf courses treated with Tourney Fungicide

Re-entry activity	Peak TTR ($\mu g/cm^2$)[1]	Transfer Coefficient (cm^2/hr)[2]	Dermal Exposure (mg/kg bw/day)[3]	MOE[4]
Golfing (females 13–49)	0.0728	450	0.00211	14194

[1] Calculated based on 1.3% TTR on day of application, from the Michigan TTR study
[2] Transfer coefficient is the golfing transfer coefficient (500 cm^2/hr), adjusted for the difference between surface area of females 13–49 and adults
[3] Dermal Exposure = (Peak TTR × Transfer Coefficient × 4 hours/day)/(62 kg bw for females 13–49 × 1000 µg/mg)
[4] Based on NOAEL= 30 mg/kg bw/day, target MOE = 1000

For the cancer risk assessment for golfers, dermal exposure was assessed for youth and adults to calculate lifetime cancer risk. Golfers were assumed to be exposed to metconazole residues when golfing for 14 days per year. Exposure was estimated using the TWA TTR, which was calculated over 30 days postapplication using the TTR values from the submitted studies (1.3% of the application rate transferable on the day of application and 49.1% daily dissipation). The same activity-specific transfer coefficients and exposure duration were used in the non-cancer and cancer risk assessments.

To calculate the potential lifetime exposure of re-entry workers to metconazole residues as a consequence of postapplication activities, exposures were amortized over an individual's lifetime. This was expressed as the LADD and takes into account the frequency of exposure throughout the individual's lifetime. Individuals are assumed to golf for 6 years as a youth and 50 years as an adult, and have a life expectancy of 75 years. The cancer risk was estimated by multiplying the LADD by the q_1^* value of $8.00 \times 10^{-3}(mg/kg\ bw/day)^{-1}$. The lifetime cancer risk for golfers is below 1×10^{-6}, which is considered not a risk of concern for the general population. Considering the non-cancer and cancer risk estimates, risk is not of concern when golfers re-enter treated turf after sprays have dried.

Table 3.4.3.2.2. Postapplication exposure and cancer risk estimates for golfers re-entering golf courses treated with Tourney Fungicide

Re-entry activity	TWA TTR ($\mu g/cm^2$)[1]	TC (cm^2/hr)[2]	Body weight (kg)	ADD (mg/kg bw/day)[3]	Days of exposure per year	Years of exposure	LADD (mg/kg bw/day)[4]	Cancer risk[5]
Youth golfers	0.005	344	39	3.66E-05	14	6	1.12E-07	9E-10
Adult golfers	0.005	500	70	2.97E-05	14	50	7.58E-07	6E-09
Lifetime							8.71E-07	7E-09

[1] TWA TTR = 30-day time-weighted average TTR, after application
[2] TC = Transfer coefficient for golfing. Note that golfing transfer coefficient for youth was adjusted for the surface area of youth and adults
[3] ADD = average daily dose
= (TWA TTR × TC × 8 hours/day × 21% dermal absorption)/(Body weight × 1000 µg/mg)
[4] LADD = lifetime average daily dose

= (ADD × Days of exposure/yr × Years of exposure) / (365 days/year × 75 years life expectancy)

[5] Cancer risk = LADD × q_1*; q_1* = 8.00×10^{-3}

3.4.3.3 Aggregate Exposure

Golfers may be exposed to metconazole through dietary exposure, since metconazole is registered for use on food crops. Since non-cancer risk (based on developmental effects) and cancer risk can come from both dermal and dietary exposure, a risk assessment was conducted aggregating dermal exposure from golfing and chronic exposure from food and drinking water. For non-cancer aggregate risk, the risk from dermal exposure for female golfers 13–49 years was combined with the risk from chronic dietary and drinking water exposure for females 13–49 years. The non-cancer aggregate risk assessment for golfers is presented in Table 3.4.3.3.1. The calculated MOE exceeds the target MOE of 1000 and risk is not of concern.

Table 3.4.3.3.1. Aggregate non-cancer risk estimate for golfers re-entering golf courses treated with Tourney Fungicide

	Exposure (mg/kg bw/day)		MOE[3]		
Re-entry activity	**Dermal[1]**	**Chronic Dietary + Water[2]**	**Dermal**	**Chronic Dietary + Water**	**Combined**
Golfing (females 13–49)	0.00211	0.000696	14194	2874	2390

[1] Dermal Exposure from Table 3.4.3.2.1

[2] Chronic dietary + drinking water exposure for females 13–49 years

[3] MOEs are based on dermal NOAEL = 30 mg/kg bw/day, target MOE = 1000, and dietary NOAEL= 2 mg/kg bw/day, target MOE = 1000
Combined MOE = 1/[(1/dermal MOE) + (1/dietary + water MOE)]; target MOE = 1000

As presented previously, cancer risk for golfers from dermal exposure is not of concern. With the lifetime cancer risk of 7×10^{-9}, cancer risk from dermal exposure from golfing is a negligible component in the aggregate cancer risk assessment for golfers. As such, the aggregate cancer risk assessment for golfers was not conducted.

3.4.3.4 Bystander Exposure and Risk

Risk to bystanders is considered negligible as exposure to spray drift is not expected to exceed the exposure for mixers/loaders and applicators.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

Please refer to Evaluation Report ERC2011-02-*Metconazole* for a summary of the previously reviewed data and the rationale for the regulatory decision. The information captured herein only relates to the changes in dietary exposure due to the (1) modification in the drinking water assessments to support the registration of metconazole for use on turf in Canada, and (2) the modification of the toxicological endpoint (q_1*).

3.5.2 Dietary Risk Assessment

Acute and chronic (cancer and non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.14), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic non-cancer analysis: Supervised trial median residues (STMdRs), experimental processing factors where available, domestic predicted percent crop treated data and anticipated residues for animal matrices. The refined chronic dietary exposure from all supported metconazole food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 13% of the ADI. Aggregate exposure from food and water is considered acceptable. The PMRA estimates that the chronic dietary exposure to metconazole from food and water is 18.0% (0.000791 mg/kg bw/d) of the ADI for the total population. The highest exposure and risk estimate is for all infants less than one year old at 55.4% (0.002436 mg/kg bw/d) of the ADI.

The refined chronic cancer risk assessment was conducted with the same criteria used for the chronic non-cancer assessment. The lifetime cancer risk from exposure to metconazole in food and drinking water was estimated to be 6×10^{-6} for the general population, which is considered acceptable due to the conservatism in the determination of the toxicological endpoint and the following assumptions and uncertainties inherent in the current drinking water assessments:

- The EECs modeled on the turf scenario (Level 1, limited refinement) were used to determine drinking water estimates. They reflect standard conservative modeling practices, using conservative inputs with respect to application rate and timing, and geographical scenarios;
- The additive effect of using 80 and 20 percentiles of multiple study values for modelling inputs such as degradation and adsorption results in conservatism; in addition, the vulnerability of scenario soil is unknown;
- Groundwater modelling provides a point source estimate of pesticide concentration as it enters the water table and does not allow for dilution with depth or distance to a water intake such as a well. The actual drinking water will most likely have lower residues than estimated given the further dilution of water as it reaches the drinking water sources;
- In the current assessment, groundwater estimates were considered as the sole drinking water source. A single source of drinking water for every day of the year is unlikely; not only are different sources of groundwater used, but a mix of ground and surface water is likely. Given that the surface water estimates of yearly average concentrations were four times lower than groundwater estimates, analysis with groundwater estimates results in a notably protective assessment.
- For groundwater modelling, percent crop area is not considered in regards to the scope or ratio of treated area within a larger aquifer or reservoir recharge area;

- Yearly pesticide application in the same field for 50 years is assumed, which is highly conservative;
- Dietary intake assumes daily intake over lifetime (70 years);
- Any potential effect from water treatment is unknown.

3.5.2.2 Acute Dietary Exposure Results and Characterization

A refined acute dietary exposure assessment was conducted using maximum field trial residue values, anticipated residues in livestock matrices and predicted percent crop treated data for blended commodities only. Aggregate exposure from food and water is considered acceptable and below PMRA's level of concern (LOC). Specifically, an acute dietary exposure of 82.0% of the ARfD was obtained for females 13 to 49 years old. For all other representative population subgroups, an acute reference dose was not established; therefore an acute dietary intake estimate was not required.

3.5.3 Aggregate Exposure and Risk

Given that turfgrass in golf courses can be treated with metconazole, there is potential for aggregate exposure to metconazole during activities related to golf. An aggregate risk assessment for metconazole was conducted to include the exposure from food and drinking water sources and the use on golf courses. The aggregate exposure for golfers, including the sum of the chronic dietary exposure (from food and drinking water) and the dermal exposure incurred at the golf course for adults and youth, are not of health concern.

3.5.4 Maximum Residue Limits

Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for metconazole.

The nature of the residues in animal and plant matrices, analytical methodology and residue trial data were assessed under ERC2011-02. The acute and chronic (cancer and non-cancer) dietary risk estimates are summarized in Appendix I, Table 3.

4.0 Impact on the Environment

The fate and environmental behaviour of metconazole, as well as its impacts on non-target terrestrial and aquatic organisms, have been previously assessed for foliar use on agricultural crops (for details see Evaluation Report ERC2011-02). The ecotoxicity data required as a condition of registration (chironomids and the full life cycle of freshwater fish) have been submitted and reviewed. These data satisfy the environmental assessment requirements for metconazole on both turf and agricultural crops.

4.1 Fate and Behaviour in the Environment

Additional fate data were provided, subsequent to the original review, and the following is a summary of the evaluation of these studies.

A laboratory study of biotransformation in soil showed significantly shorter half-lives in aerobic soil (88.7 days at 20°C and 537 days at 10°C) compared to estimates from previously submitted data of 618–661 days at 20°C (Evaluation Report ERC 2011-02). The 80th percentile of all aerobic soil biotransformation DT_{50} values (including newly submitted data combined with previously submitted data) resulted in a revised aerobic soil dissipation half-life of 492 days.

Two Canadian terrestrial field dissipation studies were conducted in Ontario and Saskatchewan on bare soil plots and showed that metconazole is persistent in the upper layers of soil (0-15 cm depth), and that residues are detected up to the last sampling date of 478 days post-treatment. The nature of the residue detections (decreasing concentrations followed by increases over the sampling period) made the calculation of DT_{50} values problematic. However, it is evident that metconazole is persistent with half-lives of approximately 140 days (Ontario) and 320 days (Saskatchewan). Approximately 7% carryover can be expected into the next growing season based on the Ontario field study, and 20–64% in the Saskatchewan field study.

Three turfgrass field dissipation studies (two in Nova Scotia and one in Oregon, a relevant northern US EcoRegion) were also reviewed. The majority of residue detections (94–97%) occurred in thatch (consisting of green grass, grass clippings, turf and roots). Residues were, however, detectable in both soil (0–15 cm depth) and thatch up to the last sampling date, which occurred approximately one year post-treatment, supporting other results which show that metconazole can persist in soil layers. Carryover (sum of thatch + soil) ranged from 5–12%. Similar to bare soil studies, the decreasing and then increasing residue concentrations, in addition to the presence of the thatch layer on the soil surface (creating an additional potential dissipation route via movement between thatch and soil), prevented the calculation of meaningful soil DT_{50} values.

Overall, the terrestrial field data reviewed for this submission indicated that metconazole is persistent, and carryover of residues to subsequent growing seasons may be greater with late season (fall) applications. Approximately 12% carryover to the next growing season was observed for the late fall application, and 5–7% for multiple applications made in mid-to-late summer. For all five study sites, only low concentrations of transformation products M11, M21 and M30 were measured during the study period. The persistence of metconazole in upper soil layers, low residue detections of transformation products, and carryover to the next growing season are consistent with previously submitted field dissipation studies (ERC 2011-02).

A summary of the terrestrial environmental fate and behaviour of metconazole derived from the new study data can be found in Appendix 1, Table 4.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are calculated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (that is, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the LOC. If the screening level risk quotient is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The environmental risk assessment for turf use of metconazole was conducted using the initially proposed application rate (a seasonal maximum of 2240 g a.i./ha as a single application, equivalent to a seasonal maximum of 4480 g end-use product/ha). The use rate for Tourney Fungicide was later finalized to be a single application of 560 g a.i./ha. The lowering of the application rate does not change which organisms may be at risk; however the magnitude of these risks will decrease. As such, the risk assessment was not revised using the lower rate except for buffer zones, which were determined based on the revised rates.

4.2.1 Risks to Terrestrial Organisms

Metconazole enters the environment when used as a fungicide on agricultural crops and on turfgrass. A comprehensive ecological risk assessment for the foliar use of metconazole on non-target terrestrial organisms has previously been conducted. The current risk assessment on turf utilized the identical suite of terrestrial organisms as in the original assessment (ERC 2011-02).

Terrestrial organisms, such as earthworms, honeybees, birds, small wild mammals and terrestrial plants, may be exposed to Tourney Fungicide in the environment through direct contact with treated material, contact with spray drift, or (in the case of birds and mammals) from ingestion of contaminated food. The screening level risk quotients for Tourney Fungicide were based on the initially proposed seasonal maximum application rate (a single application of 2240 g a.i./ha).

The ecological risk assessment of metconazole to terrestrial organisms was conducted by first evaluating the ecotoxicity data for invertebrates, vertebrates and plants. After determining the most sensitive ecotoxicity endpoints (ERC2011-02, Appendix I, Table 16), these values were then used in the screening level risk assessment (Appendix I, Tables 5 and 6). In those cases where the screening level assessments resulted in the LOC being exceeded, a refined assessment was conducted to further characterize the risk to terrestrial organisms (Appendix I, Tables 7 and 8).

Terrestrial Invertebrates: The proposed use of metconazole is not expected to pose a risk to terrestrial invertebrates including earthworms and honeybees. Previously analyzed studies displayed negligible toxicity of metconazole to these groups of organisms (ERC2011-02). At a seasonal maximum use rate of 2240 g a.i./ha on turf, the LOC is still not exceeded.

Non-target plants: Some toxicity to non-target terrestrial plants can be expected as phytotoxic effects were demonstrated after a single application of metconazole (ERC2011-02). The LOC is exceeded for the proposed use on turf at the screening level and when the exposure is refined for drift (6% drift deposition for ground application with a medium spray droplet size based on the ASAE classification).

Birds and mammals: The toxicity of metconazole to birds and small wild mammals has previously been established. On an acute basis, the toxicity of metconazole ranges from slight to moderate for birds. On a reproductive basis, ecologically relevant effects include decreased hatching success, chick survival and chick body weights. Metconazole is highly toxic to mice and displays low to moderate toxicity to rats (Evaluation Report ERC2011-02-*Metconazole*, Appendix I, Table 16).

For the bird and mammal risk assessment, the ingestion of food items contaminated by spray droplets is considered to be the main route of exposure. The risk assessment is thus based on the estimated daily exposure which takes into account the expected concentration of metconazole on various food items immediately after the last application and the food ingestion rate of different sizes of birds and mammals. At the screening level, the most conservative exposure estimate is used (100% of the bird or mammal's diet consists of food items showing the highest level of contamination after application in the treated area). In addition, acute toxicity values are divided by an uncertainty factor of 10 to account for differences in inter- and intra-species sensitivity.

The LOC for the newly proposed use on turf is exceeded for birds and mammals for both acute and reproductive effects.

In order to further characterize the risk to birds and mammals, the assessment was expanded to include a range of metconazole residue concentrations on all relevant food items. Also, both on-

and off-field exposure estimates were considered. The off-field exposure takes into account the projected drift deposition at one metre downwind from the site of application.

Birds – On-field: When using mean (rather than maximum) residues, the acute LOC is no longer exceeded for all three size groups and for all feeding guilds of birds. However, the reproductive LOC is still exceeded. In the case of both small and medium birds, the LOC for reproduction is exceeded for all feeding guilds. In the case of large birds, the reproductive risk is still exceeded for herbivores, frugivores, and insectivores preying on small insects.

Birds – Off-field: When considering the off-field risk to birds, the LOC is no longer exceeded on an acute and reproductive basis for all three size groups of birds and for all feeding guilds. The one exception is a slight reproductive risk for small insectivorous birds feeding on small insects when using maximum nomogram residues. However, it decreases to below LOC when mean nomogram residues are used.

Mammals – On-Field: When using mean (rather than maximum) residues, the acute LOC is no longer exceeded for both small and large sized mammals for all feeding guilds. However, the acute LOC is exceeded in some cases for medium sized mammals. In the case of medium sized herbivores foraging on short grass (which is extremely relevant to the proposed use of metconazole on turf), the LOC is exceeded. For reproductive effects, the LOC is exceeded for some feeding guilds and not for others. For small mammals, the LOC is exceeded for insectivores and frugivores. For both medium and large mammals, the LOC is exceeded for some insectivores, frugivores and all herbivores.

Mammals – Off-Field: When assessing the off-field risk, considering both maximum and mean residues, the acute LOC is no longer exceeded for all three size groups of mammals and for all feeding guilds. When using maximum residues, the reproductive LOC for off-field effects is exceeded for certain feeding guilds of medium sized mammals: i.e. herbivores foraging on short grass (which is extremely relevant to the proposed use of metconazole on turf) when using maximum residues. However, when using mean nomogram residues, reproductive effects are no longer above the LOC.

Given that most of the risk quotient exceeded the LOC by a relatively small margin when considering maximum residues, and that the risk quotients are often below the LOC when considering mean residues, the likelihood of adverse effects on birds and mammals is considered to be relatively low. Furthermore, the LOC is not exceeded in almost all cases for off-field exposure, which is where the majority of bird and mammals populations reside.

To address the potential sensitivity of terrestrial plants to exposure of metconazole, terrestrial spray buffer zones were determined based on the turf use pattern. Details on the required size of the terrestrial buffer zones are provided on the Tourney Fungicide label and in Appendix I, Table 9.

4.2.2 Risks to Aquatic Organisms

Although the use of metconazole on turf does not include direct application to water, the possibility that aquatic systems will be exposed to metconazole, directly or indirectly, cannot be ruled out. Metconazole may enter the aquatic environment through spray drift and/or runoff. Also, pesticides that are bound to soil particles may enter aquatic environments through soil erosion. Since metconazole has a tendency to adsorb to soil, this latter route of exposure may potentially be a source of contamination of aquatic environments.

A comprehensive ecological risk assessment for the foliar use of metconazole on non-target aquatic organisms has previously been conducted. The current risk assessment on turf utilized the identical suite of aquatic organisms as in the original assessment (ERC2011-02) along with two additions: chironomids and early life stages of fathead minnow (Appendix 1, Table 10).

The current assessment was conducted by first evaluating the ecotoxicity data to determine the most sensitive ecotoxicity endpoints. These values (Appendix 1, Table 10; and ERC2011-02, Appendix I, Table 17) were then used in the screening level risk assessment (Appendix I, Table 11). In those cases where the screening level assessments resulted in the LOC being exceeded, a refined assessment was conducted in order to further characterize the risk to aquatic organisms (Appendix I, Tables 12 and 13). Whereas the screening level assessment assumes a direct overspray to a water body, the refined assessment identifies the risk from drift and runoff exposure in freshwater and marine ecosystems.

Freshwater Invertebrates: Previously analyzed toxicity studies demonstrated acute moderate toxicity to the fresh water flea, *Daphnia magna*, as well as effects on reproduction (ERC2011-02). At the use rate of 2240 g a.i/ha on turf, the LOC is not exceeded on an acute basis, however, it is exceeded for reproductive effects at the screening level. Nevertheless, once the risk is refined for drift and runoff, the LOC for reproductive effects is no longer exceeded.

New information has been provided for the ecotoxicity of sediment containing metconazole to chironomids. Compared to control values, the mean ash-free dry weight and percent emergence were not affected by metconazole exposure. Survival was affected only in the highest test concentration (100 mg a.i./kg). As mortality did not exceed 50% at any level, the 10-day LC_{50} value for mortality was estimated to be > 100 mg a.i./kg. The NOEC for mortality was 50 mg a.i./kg. The corresponding porewater concentrations were > 7.1 mg a.i./L (LC_{50}) and 5.6 mg a.i./L (NOEC). For the proposed use on turf, the LOC is not exceeded for chironomids.

Freshwater Fish: Previously analyzed toxicity studies demonstrated acute moderate toxicity to both rainbow trout and fathead minnow at the juvenile life stages of growth. Chronic effects were seen at very low metconazole concentrations, and the most sensitive aquatic organism was the early life stage of rainbow trout (ERC2011-02).

New information has been provided on the full life cycle (egg to egg) of the fathead minnow where survival, appearance and behaviour, growth and reproduction were observed over two generations. The NOEC for mortality, reproduction, growth and liver toxicity was determined to be 0.0032 mg a.i./L. Although the LOC is exceeded for the full life cycle of the fathead minnow;

the RQ values are similar to (and slightly lower than) those established for the early life stage of rainbow trout. As the ELS rainbow trout was previously identified as the most sensitive aquatic organism, the outcome of the aquatic risk assessment is not altered by the new study data.

The acute LOC is not exceeded for juvenile stages of fathead minnow. Although the LOC is exceeded for juvenile stages of rainbow trout on an acute basis at the screening level, it is no longer exceeded once the risk is refined for drift and runoff. However, for early life stages of both these species, the LOC is exceeded even when drift and runoff are taken into account.

Freshwater Algae: The toxicity of metconazole to these groups of organisms has previously been determined (ERC2011-02). The LOC is exceeded on an acute basis at the screening level. However, once drift and runoff are incorporated into the risk determination, the LOC is no longer exceeded.

Aquatic Vascular Plants: The toxicity of metconazole to *Lemna gibba* has previously been determined (ERC2011-02). On an acute basis, the LOC is exceeded, even when drift and runoff are taken into account.

Amphibians: As in the original metconazole assessment, the risk to amphibians was determined using surrogate data from the acute and chronic ELS studies on rainbow trout. The LOC is exceeded on both an acute and chronic basis at the screening level. The same is true for the risk determination for metconazole runoff. For spray drift of metconazole, the LOC is exceeded on a chronic basis, but not on an acute basis.

Marine/estuarine fish, algae and invertebrates: The toxicity of metconazole to these groups of organisms has previously been determined (ERC2011-02). The LOC is not exceeded for marine fish (sheepshead minnow), marine diatoms (*Skeletonema costatum*), and the eastern oyster.

At the screening level assessment, the LOC is not exceeded for mysid shrimp on an acute basis; however, it is exceeded on a chronic (reproductive) basis. Once spray drift is included in the risk determination, the LOC for reproductive effects is no longer exceeded. However, when examining the potential risk from runoff, the LOC is exceeded for reproductive effects on the mysid shrimp.

To address the potential sensitivity of amphibians, early life stages of freshwater fish, and aquatic vascular plants to exposure of metconazole; aquatic spray buffer zones were determined based on the turf use pattern. Details on the size of the required freshwater and marine spray buffer zones are provided on the Tourney Fungicide label and in Appendix I, Table 9.

5.0 Value

5.1 Effectiveness Against Pests

A total of 38 efficacy trials were submitted to support the proposed claims. Thirteen of the trials tested more than one disease. Eight trials were not reviewed because the product was not applied

according to the proposed use pattern or disease pressure was too low to evaluate the level of control. Results from the efficacy trials demonstrated acceptable efficacy of Tourney Fungicide against all the proposed diseases at rates of 8.4–11.2 g/100 m^2. Tourney Fungicide demonstrated equivalent or better efficacy compared to the tested commercial standards registered to control these diseases. As there are numerous alternative fungicides registered to control or suppress the labelled diseases, a single application of Tourney Fungicide can easily be integrated into a turf disease management program to contribute to efficacy and resistance management. Therefore, the claims for control of dollar spot, anthracnose basal rot, anthracnose foliar blight, pink snow mould and grey snow mould are supported. Tourney Fungicide must be tank mixed with chlorothalonil to control pink and grey snow moulds.

5.2 Phytotoxicity to Host Plants

Tourney Fungicide was tested on annual bluegrass, creeping bentgrass, colonial bentgrass, and Kentucky bluegrass. No phytotoxic effects or negative effects on growth were noted in the trials. The label includes a statement warning that applications of Tourney Fungicide can injure golf course greens that are under high heat (air temperature exceeding 32°C) and/or drought stress.

5.3 Economics

According to a golf industry study, 5.95 million Canadians currently play golf, representing a national golf participation rate of 21.5%; among the highest golf participation rate of any country in the world. Overall, this community spends a projected $12.9 billion dollars per calendar year on direct golf expenditures. In Ontario, 7000 people are employed for the management of turfgrass on golf courses. The Ontario golf courses collectively spend $375 million dollars on operating and equipment expenses. A quality playing surface is a driver for the industry and pest control products contribute to achieving the goal.

Generally, turf managers do not use economic thresholds for fungicide application to turf but predictive models may aid in timing for certain diseases, such as dollar spot and brown patch. Turf diseases are generally treated preventatively as the appearance of diseases on golf greens and other high maintenance areas can affect the quality of play. Once damaged, the cost of renovating putting surfaces (seed, fertility, labour and the investment of time) exceeds the cost of preventative control. Control of snow mould diseases ensures earlier turf growth in spring; this allows earlier play, which can be economically important for public golf courses. Sod farms must produce turf in a harvestable form with a dense root system that meets the specifications of the Nursery Sod Growers Association. The aesthetic quality of the end product is also important to home owners and managers of commercial areas, municipal areas and golf courses that purchase their product. Preventing turf damage on golf courses and sod farms also prevents weed encroachment, further reducing economic inputs.

5.4 Sustainability

5.4.1 Survey of Alternatives

A number of fungicides are registered on turf to control or suppress diseases on the Tourney Fungicide label. Refer to Appendix I, Table 14 for further information on alternative products.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Integrated pest management (IPM) in turf management encourages the growth of healthy turf plants that can tolerate disease infection and discourages pathogen growth and spread to other areas of the golf course or sod farm. The preventative use of Tourney Fungicide contributes to current IPM practices by reducing pathogen growth early in the disease cycle, which also reduces the chance of the disease spreading to new turf areas.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Metconazole is a triazole fungicide (Group 3) with a moderate risk for resistance development. Resistance can be managed by using tank mixtures and appropriate rotation with fungicides with a different mode of action. To limit the potential for the development of resistant populations, Group 3 fungicides should be alternated with fungicides with a different mode of action.

5.4.4 Contribution to Risk Reduction and Sustainability

Fungicides from different mode of action groups are registered to control or suppress the turf diseases on the Tourney Fungicide label. Fungal populations resistant to benzimidazole fungicides (Group 1) have been identified in the United States. Although other group 3 fungicides are registered for these diseases, metconazole provides turf managers with a new active ingredient for rotation and tank mixing to manage resistance.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the original review process, metconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The TSMP conclusions reached at that time apply to the current submission:

• Metconazole does not meet all Track 1 criteria, nor does it form any transformation products that meet all Track 1 criteria, and therefore is not considered a Track 1 substance. See Table 6.1.1, for comparison with Track 1 criteria.

Table 6.1.1 Toxic Substances Management Policy Considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Yes. 492 days
	Water	Half-life ≥ 182 days	No. 0.81–15.9 days
	Sediment	Half-life ≥ 365 days	Yes. 534 days (sediment) 900 days (total system)
	Air	Half-life ≥ 2 days or evidence of long range transport	No. Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure ($< 1.23 \times 10^{-5}$) and Henry's law constant (2.08×10^{-9} atm-m^3- mol^{-1}).
Bioaccumulation[4]	Log $K_{OW} \geq 5$		No. Log $K_{OW} = 3.85$
	BCF ≥ 5000		No. BCF = 63 (fillet) and BCF = 218 (viscera)
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No. Does not meet all four TSMP Track 1 criteria.

[1]All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4]Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the current revised environmental review process, contaminants in the technical and formulants and contaminants in the end-use products were compared against the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

• Technical grade metconazole does not contain any formulants or contaminants of health or environmental concern identified in the Canada Gazette.

• The end-use product Tourney Fungicide does not contain any formulants of health or environmental concern identified in the Canada Gazette.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for metconazole is adequate to define the majority of toxic effects that may result from exposure. In short- and long-term toxicology studies on laboratory animals, target organs were the liver, adrenals, reproductive organs and haematopoeitic systems. In dogs, the eye is also a target. There was no evidence of immunotoxicity. Metconazole shows durational effects in all species. In mice, tumours were seen in the liver of both males and females, which were considered to have a threshold; however, male mice exhibited a dose-related increase in skin sarcomas at all doses tested. There was no evidence of genotoxicity. When administered to pregnant rabbits either via the oral or dermal routes, craniofacial malformations were observed at doses that did not elicit maternal toxicity and limb-flexure malformations were specific to the dermal route. In pregnant rats given metconazole orally, spinal malformations were observed at maternally toxic doses.

Please refer to ERC2011-02 for the food residue summary of metconazole.

Mixer/loaders and applicators handling Tourney Fungicide and workers re-entering treated golf courses and sod farms are not expected to be exposed to levels of metconazole that will result in risks of concern when Tourney Fungicide are used according to label directions. The personal protective equipment on the product label are adequate to protect workers.

Exposure to golfers re-entering treated golf courses is not expected to result in risks of concern when Tourney Fungicide is used according to label directions.

7.2 Environmental Risk

Current environmental risk assessment methodology was used to conduct the screening level and refined risk assessment for metconazole fungicide use on turfgrass, including an evaluation of risk from spray drift and runoff. Using the previously evaluated information in ERC2011-02, as well as the additional environmental fate and ecotoxicological studies provided, it has been determined that there are potential risks to aquatic organisms, non-target terrestrial plants, birds, and small wild mammals. It has been determined that spray buffer zones of 5 m or less are adequate to mitigate risk to non-target organisms resulting from metconazole spray drift resulting from use on turfgrass. Spray buffer zones will not mitigate runoff. To reduce the potential for runoff of metconazole to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are required. In addition, a vegetative strip between the area and the edge of a water body is recommended to reduce runoff of metconazole to aquatic areas.

Previously identified data gaps included two ecotoxicity studies were requested: sediment exposure of chironomids to metconazole, and a full life cycle toxicity test (i.e. egg to egg) for all life stages of fish and the need to further characterize the risk to aquatic organisms (ERC2011-02). These data were submitted in the support of the current registration and were found to be acceptable.

7.3 Value

Due to the high expectations of turf managers with respect to the aesthetic quality of their product, it is important to maintain the sustainability of pest control programs by introducing new active ingredients for integration into IPM programs. The registration of metconazole for use on turfgrass provides growers with another tool to control diseases and manage resistance.

The efficacy data were sufficient to support the disease claims. Tourney Fungicide must be tank mixed with chlorothalonil to control pink and grey snow moulds. A summary of the proposed and supported uses for Tourney Fungicide is presented in Appendix I, Table 15.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Metconazole Technical Fungicide and Tourney Fungicide, containing the technical grade active ingredient metconazole, to control several diseases on turfgrass in golf courses and sod farms.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
A	applying
ADD	average daily dose
ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATPD	area treated per day
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
bwg	body weight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetres
CR	chemical resistant
d	day(s)
DALA	days after last application
DF	dry flowable
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{25}	effect concentration 25%
EC_{50}	effect concentration 50%
EDE	estimated daily exposure
EEC	expected environmental concentration
g	gram
GB	groundboom
ha	hectare(s)
hr	hour(s)
IC_{50}	inhibitory concentration 50%
IgM	Immunoglobin "M"
IPM	integrated pest management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LADD	lifetime average daily dose
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection

m	metre(s)
mg	milligram
mL	millilitre
ML	mixing/loading
MLA	mixer/loader/applicator
MOA	mode of action
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect-level
NZW	New Zealand white
ORETF	Outdoor Residential Exposure Task Force
Pa	pascal(s)
PCPA	*Pest Control Product Act*
PHED	Pesticide Handlers Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRZM-EXAMS	Pesticide Root Zone Model – Exposure Analysis Modelling System
q_1*	cancer potency factor
R/A	risk assessment
REI	restricted-entry interval
RQ	risk quotient
SRBC	sheep red blood cell
STMdR	supervised trial median residues
TC	transfer coefficient
TP	transformation products
TSMP	Toxic Substances Management Policy
TTR	transferable turf residue
TWA	time-weighted average
US	United States
UV	ultraviolet
WG	wettable granule
yrs	year

Appendix I Tables and Figures

Table 1 Toxicity Profile of Technical Metconazole

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

Please refer to Evaluation Report ERC2011-02, *Metconazole* with the following addition.

Study Type/Animal/PMRA #	Study Results
Rabbit Dermal Developmental Toxicity Study NZW Rabbits PMRA #2191625	**Skin Irritation Maternal LOAEL: 90 mg/kg bw/day** **Skin Irritation Maternal NOAEL: 30 mg/kg bw/day** **Systemic Maternal LOAEL: 270 mg/kg bw/day** **Systemic Maternal NOAEL: 90 mg/kg bw/day** **≥ 90 mg/kg bw/day:** skin irritation **270 mg/kg bw/day:** ↓ bwg (↓31%), food consumption, ↑ total and late resorptions, ↑ postimplantation loss **Developmental LOAEL: 90 mg/kg bw/day** **Developmental NOAEL: 30 mg/kg bw/day** **≥ 90 mg/kg bw/day:** craniofacial and limb flexure malformations
Immunotoxicity Study Crl:WI(Han) rats (males only) PMRA #1926048	**NOAEL:** 17 mg/kg bw/day in males 52 mg/kg bw/day: ↓ bw/bwg **Immunotoxicity (IgM response to Sheep Red Blood Cell (SRBC))** No evidence of immunotoxicity

Table 2 Toxicology Endpoints for Use in Health Risk Assessment for Metconazole

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary females ages 13–49	PMRA #1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw Increased craniofacial malformations and liver variations.	1000
	ARfD (♀ 13–49) = 0.002 mg/kg bw		
Acute dietary general population	Not required		
Chronic dietary females ages 13–49	PMRA #1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw/day Increased craniofacial malformations and liver variations.	1000
	ADI (♀ 13–49) = 0.002 mg/kg bw/day		
Chronic dietary general population	Combined Oral Rat Chronic and Oncogenicity Studies	NOAEL = 0.44 mg/kg bw/day Increased vacuolation of the adrenal cortex in males and females and necrotic inflammatory foci and clear cell foci in the liver of males	100
	ADI (gen pop) = 0.0044 mg/kg bw/day		
Short-term & Intermediate-term dermal	Rabbit Dermal Developmental Toxicity Study	NOAEL = 30 mg/kg bw/day Increased craniofacial and limb flexure malformations	1000
Short-term & Intermediate-term inhalation[2]	PMRA #1405646 Rabbit Oral Developmental Toxicity Study	NOAEL = 2 mg/kg bw/day Increased craniofacial malformations and liver variations.	1000
Cancer	Based on skin fibromas/sarcomas in male mice $q_1^* = 8.0 \times 10^{-3}$ (mg/kg bw/day)$^{-1}$		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational assessments

[2] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Table 3 Food Residue Chemistry Overview of Risk Assessment

DIETARY RISK FROM FOOD AND WATER		
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**
		Food and Water
Refined chronic non-cancer dietary risk **ADI (females 13–49 yrs) = 0.002 mg/kg bw/day** **ADI (all other subpopulations) = 0.0044 mg/kg bw/day** **Estimated chronic drinking water concentration = 30 μg a.i./L**	**All infants <1 year**	55.4
	Children 1–2 years	33.8
	Children 3–5 years	29.5
	Children 6–12 years	19.6
	Youth 13–19 years	13.6
	Adults 20–49 years	15.9
	Adults 50+ years	16.6
	Females 13–49 years	34.8
	Total population	18.0
Refined acute dietary exposure analysis, 95th percentile **ARfD (females 13–49 yrs) = 0.002 mg/kg bw** **Estimated acute drinking water concentration = 30 μg a.i./L**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**
		Food and Water
	Females 13–49 years	82.0
Basic cancer dietary risk **q_1^* = 0.008 (mg/kg bw/day)$^{-1}$** **Estimated chronic drinking water concentration = 30 μg a.i./L**	**POPULATION**	**ESTIMATED RISK**
		Food and Water
	Total population	6.3×10^{-6}

Table 4 Fate and Behaviour in the Terrestrial Environment – New Study Data (Additional to Evaluation Report ERC2011-02, *Metconazole*)[1]

Property	Test Substance	Value and Description	Transformation Products (TP)	Comments
Laboratory Biotransformation Studies				
Biotransformation in aerobic soil **Sandy loam** soil (pH 6.2, organic carbon 2.2%)	metconazole	<u>New data at 20°C</u> DT_{50}: 88.7 days DT_{90}: 295 days - moderately Persistent <u>New data at 10°C</u> DT_{50}: 537 days DT_{90}: 1783 days - persistent <u>80th percentile of all data combined –</u> DT_{50}: 492 days - persistent	No Major TP. Minor TP Only: CL 382839 and two unknowns. All less than 5% applied.	Not an important route of transformation
Terrestrial Field Dissipation Studies				
Ontario – Bare Soil Plots	metconazole	DT_{50}: 140 days - persistent, - 7% carryover	No Major TP. Minor TP Only: Small residue detections of **M11**, **M21** and **M30**	Significant detections only in the top 0–7.5 cm layer
Saskatchewan – Bare Soil Plots	metconazole	DT_{50}: 320 days - very persistent - 20–64% carryover	No Major TP. Small residue detections of **M11**, **M21** and **M30**	Majority of detections in the top 0–15 cm layer
Nova Scotia and **Oregon** – turfgrass	metconazole	Not possible to determine reliable DT_{50} values	No major TP. Minor TP: **M11**, **M21** and **M30,** mostly in thatch.	Significant detections mostly in thatch (94–97%), not in soil

[1]For comprehensive summary tables of the environmental fate and behaviour properties of metconazole previously reviewed, see Evaluation Report ERC2011-02, *Metconazole*, Appendix I, Tables 13 and 14.

Table 5 Screening Level Risk Assessment for Non-Target Invertebrates and Plants

Organism	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value	Uncertainty Factor	Ecotox Endpoint Value used in R/A	EEC Value used in R/A	RQ Value	LOC Exceeded
Invertebrates								
Earthworm	14-day acute	**LD_{50}:** value is greater than the highest test concentration of 1000 mg a.i./kg soil	1000 mg a.i./kg	2	500 mg a.i./kg	1 mg a.i./kg soil	0.002	No
Bee	96-hour oral	**LC_{50}:** 86 µg a.i./bee (converted to 96.32 kg a.i./ha)	86	1	96.32 kg a.i./ha	2.24 kg a.i./ha	0.023	No
	96-hour oral	**$NOEC_{(mortality)}$:** 12 µg a.i./bee (converted to 13.44 kg a.i./ha)	12	1	13.44 kg a.i./ha	2.24 kg a.i./ha	0.17	No
	96-hour contact	**LD_{50}:** value is greater than the highest test concentration of 100 µg a.i./bee (converted to 112 kg a.i./ha)	100	1	112 kg a.i./ha	2.24 kg a.i./ha	0.02	No
Terrestrial Plants								
Vascular plant	Seedling emergence	**EC_{25}:** values are greater than the highest test concentration for monocots (109.8) and dicots (108.7) g a.i./ha	108.7	1	108.7	2240 g a.i./ha (single app)	20.6	Yes

Organism	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value	Uncertainty Factor	Ecotox Endpoint Value used in R/A	EEC Value used in R/A	RQ Value	LOC Exceeded
	Vegetative vigour	**EC_{25}:** values are greater than the highest test concentration for both monocots and dicots (109 g a.i./ha)	109	1	109	2240 g a.i./ha (single app)	20.55	Yes

Table 6 Screening Level Risk Assessment for Birds and Mammals

Type of Exposure	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
BIRDS				
Small Bird (0.02 kg)				
Acute	79.80	Insectivore (small insects)	112.87	1.41
Reproduction	6.07	Insectivore (small insects)	112.87	18.59
Medium Sized Bird (0.1 kg)				
Acute	79.80	Insectivore (small insects)	88.08	1.10
Reproduction	6.07	Insectivore (small insects)	88.08	14.51
Large Sized Bird (1 kg)				
Acute	79.80	Herbivore (short grass)	91.91	1.15
Reproduction	6.07	Herbivore (short grass)	91.91	15.14
MAMMALS				
Small Mammal (0.015 kg)				
Acute	56.60	Insectivore (small insects)	64.92	1.15
Reproduction	9.05	Insectivore (small insects)	64.92	7.17
Medium Sized Mammal (0.035 kg)				
Acute	56.60	Herbivore (short grass)	203.39	3.59
Reproduction	9.05	Herbivore (short grass)	203.39	22.47
Large Sized Mammal (1 kg)				
Acute	56.60	Herbivore (short grass)	108.68	1.92
Reproduction	9.05	Herbivore (short grass)	108.68	12.01

Table 7 Refined Risk Assessment for Non-Target Plants Exposed to Metconazole Spray Drift

Test substance: Exposure	Ecotox Endpoint Value (g a.i./ha)	Screening Level EEC (g a.i./ha)	Screening Level RQ	Refined EEC – Ground Drift (g a.i./ha)	Refined RQ – Ground Drift	LOC Exceeded
Tourney Fungicide: Seedling Emergence	108.7	2240 g a.i./ha (single app)	20.6	134.4	1.24	yes
Tourney Fungicide: Vegetative Vigour	109	2240 g a.i./ha (single app)	20.55	134.4	1.23	yes

Table 8 Refined Risk Assessment for Birds and Mammals

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg ai/kg bw/d)	Food Guild (food item)	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ	EDE (mg ai/kg bw)	RQ
Small Bird (0.02 kg)										
Acute	79.80	Insectivore (small insects)	112.87	1.41	6.77	0.08	62.95	0.79	3.78	0.05
	79.80	Granivore (grain and seeds)	28.22	0.35	1.69	0.02	13.46	0.17	0.81	0.01
	79.80	Frugivore (fruit)	56.43	0.71	3.39	0.04	26.92	0.34	1.61	0.02
Reproduction	6.07	Insectivore (small insects)	112.87	18.59	6.77	1.12	62.95	10.37	3.78	0.62
	6.07	Granivore (grain and seeds)	28.22	4.65	1.69	0.28	13.46	2.22	0.81	0.13
	6.07	Frugivore (fruit)	56.43	9.30	3.39	0.56	26.92	4.43	1.61	0.27
Medium Sized Bird (0.1 kg)										
Acute	79.80	Insectivore	88.08	1.10	5.28	0.07	49.12	0.62	2.95	0.04

		(small insects)								
	79.80	Insectivore (large insects)	22.02	0.28	1.32	0.02	10.50	0.13	0.63	0.01
	79.80	Granivore (grain and seeds)	22.02	0.28	1.32	0.02	10.50	0.13	0.63	0.01
	79.80	Frugivore (fruit)	44.04	0.55	2.64	0.03	21.00	0.26	1.26	0.02
Reproduction	6.07	Insectivore (small insects)	88.08	14.51	5.28	0.87	49.12	8.09	2.95	0.49
	6.07	Insectivore (large insects)	22.02	3.63	1.32	0.22	10.50	1.73	0.63	0.10
	6.07	Granivore (grain and seeds)	22.02	3.63	1.32	0.22	10.50	1.73	0.63	0.10
	6.07	Frugivore (fruit)	44.04	7.26	2.64	0.44	21.00	3.46	1.26	0.21
Large Sized Bird (1 kg)										
Acute	79.80	Insectivore (small insects)	25.72	0.32	1.54	0.02	14.34	0.18	0.86	0.01
	79.80	Insectivore (large insects)	6.43	0.08	0.39	0.00	3.07	0.04	0.18	0.00
	79.80	Granivore (grain and seeds)	6.43	0.08	0.39	0.00	3.07	0.04	0.18	0.00
	79.80	Frugivore (fruit)	12.86	0.16	0.77	0.01	6.13	0.08	0.37	0.00
	79.80	Herbivore (short grass)	91.91	1.15	5.51	0.07	32.64	0.41	1.96	0.02
	79.80	Herbivore (long grass)	56.12	0.70	3.37	0.04	18.32	0.23	1.10	0.01
	79.80	Herbivore (forage crops)	85.04	1.07	5.10	0.06	28.11	0.35	1.69	0.02
Reproduction	6.07	Insectivore (small insects)	25.72	4.24	1.54	0.25	14.34	2.36	0.86	0.14
	6.07	Insectivore	6.43	1.06	0.39	0.06	3.07	0.51	0.18	0.03

		(large insects)								
	6.07	Granivore (grain and seeds)	6.43	1.06	0.39	0.06	3.07	0.51	0.18	0.03
	6.07	Frugivore (fruit)	12.86	2.12	0.77	0.13	6.13	1.01	0.37	0.06
	6.07	Herbivore (short grass)	91.91	15.14	5.51	0.91	32.64	5.38	1.96	0.32
	6.07	Herbivore (long grass)	56.12	9.25	3.37	0.55	18.32	3.02	1.10	0.18
	6.07	Herbivore (forage crops)	85.04	14.01	5.10	0.84	28.11	4.63	1.69	0.28

Table 9 Spray Buffer Zones Required

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Turfgrass on golf course and sod farms	5	1	1	1	1

For tank mixes, consult the labels of the tank mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

Table 10 Toxicity to Non-Target Aquatic Species – New Study Data (Additional to Evaluation Report ERC2011-02, *Metconazole*)[1]

Organism	Exposure	Test Substance	Endpoint Value (mg a.i./L)
Chironomid SEDIMENT TOXICITY (New Study)	28-day chronic	metconazole	NOEC (mortality): 5.6
Fathead Minnow FULL LIFE CYCLE (New Study)	180-day chronic: Full Life Cycle	metconazole	NOEC (mortality, reproduction, growth and liver toxicity): 0.0032

[1]For comprehensive summary tables of the ecotoxicity of metconazole to non-target organisms, see Evaluation Report ERC2011-02, *Metconazole*, Appendix I, Tables 16 and 17.

Table 11 Screening Level Risk Assessment for Non-Target Aquatic Species

Organism	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Ecotox Endpoint Value (mg a.i./L) used in R/A	Water Depth (cm)	EEC value used in R/A (mg a.i./L)	RQ	LOC exceeded
Freshwater Species									
Daphnid (*Daphnia magna*)	48-hour acute	**LC_{50}**	4.2	2	2.1	80	0.28	0.13	no
	21-day chronic	**NOEC** (reproduction)	0.16	1	0.16	80	0.28	1.75	yes
Chironomid SEDIMENT TOXICITY (new study)	28-day chronic	**NOEC** (mortality)	5.6	1	5.6	80 15	0.28 1.5	0.05 0.24	no no
Rainbow Trout (*Salmo gairdneri*)	96-hour acute	**LC_{50}**	2.2	10	0.22	80	0.28	1.27	yes
	28-day Chronic-Juvenile Growth	**NOEC** (mortality and sublethal effects)	1.14	1	1.14	80	0.28	0.25	no
	95-day ELS	**NOEC** (sublethal effects)	0.009	1	0.009	80	0.28	31.1	yes
	95-day ELS	**NOEC** (body measurements and mortality)	0.0029	1	0.0029	80	0.28	96.6	yes
Fathead minnow *(Pimephales Promelas)*	96-hour acute	**LC_{50}**	3.9	10	0.39	80	0.28	0.72	no

Organism	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Ecotox Endpoint Value (mg a.i./L) used in R/A	Water Depth (cm)	EEC value used in R/A (mg a.i./L)	RQ	LOC exceeded
Fathead Minnow FULL LIFE CYCLE (New Study)	Full life cycle – 180 days	**NOEC**: mortality, repro, growth and liver toxicity	0.0032	1	0.0032	80	0.28	87.5	yes
Green Algae (*Selenastrum capricornutum*)	96-hour acute	**EC_{50}** (biomass and cell density)	0.2	2	0.1	80	0.28	2.80	Yes
Diatom (*Navicula pelliculosa*)	96-hour acute	**EC_{50}** (biomass and cell density)	0.097	2	0.0485	80	0.28	5.77	Yes
Aquatic Vascular Plant (*Lemna gibba*)	7-day acute	**EC_{50}** (frond number)	0.025	2	0.0125	80	0.28	22.4	yes
Amphibians (surrogate fish data)	Acute – Rainbow	**LC_{50}**	2.2	10	0.22	15	1.5	82	yes
	Chronic – ELS	**NOEC** (body measurements and mortality)	0.0029	1	0.0029	15	1.5	517	yes
Marine Species									
Mysid shrimp (*Mysidopsis bahia*)	96-hour acute	**LC_{50}**	0.75	2	0.375	80	0.28	0.75	no
	28-day chronic	**NOEC** (reproduction)	0.024	1	0.024	80	0.28	11.7	yes

Organism	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Uncertainty Factor	Ecotox Endpoint Value (mg a.i./L) used in R/A	Water Depth (cm)	EEC value used in R/A (mg a.i./L)	RQ	LOC exceeded
Eastern Oyster (*Crassostrea virginica*)	96-hour acute	**EC_{50}** (shell deposition)	2.3	2	1.15	80	0.28	0.24	no
Sheepshead Minnow (*Cyprinodon variegates*)	96-hour acute	**LC_{50}**	6.3	10	0.63	80	0.28	0.44	no
Diatom (*Skeletonema costatum*)	96-hour acute	**EC_{50}** (cell density)	1.7	2	0.85	80	0.28	0.33	no
	Indicates the most sensitive freshwater fish acute and chronic endpoints (LC50 and NOEC).								
	These studies were used as surrogate data for the amphibian risk assessment.								
	Indicates that a refined risk assessment is required.								

Table 12 Refined Risk Assessment for Non-Target Aquatic Organisms Exposed to Metconazole Spray Drift

Sensitive Aquatic Organisms	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Water Depth (cm)	Refined Drift EEC (mg a.i./L)	Refined RQ	LOC exceeded
Freshwater Species							
Daphnid,	21-day chronic	**NOEC**: reproduction	0.16	80	0.0168	0.11	no
Rainbow Trout	96-hour acute	**LC_{50}**	2.2	80	0.0168	0.0076	no
	95-day ELS	**NOEC:** (sublethal effects)	0.009	80	0.0168	1.87	yes
	95-day ELS	**NOEC (body measurements and mortality)**	**0.0029**	**80**	**0.0168**	**5.79**	**yes**
Fathead Minnow FULL LIFE CYCLE (New Study)	Full life cycle – 180 days	**NOEC**: mortality, repro, growth and liver toxicity	0.0032	80	0.0168	5.25	yes
Green Algae	96-hour acute	**EC_{50}** (biomass and cell density)	0.1	80	0.0168	0.168	no
Diatom	96-hour acute	**EC_{50}** (biomass and cell density)	0.0485	80	0.0168	0.346	no
Lemna gibba	7-day acute	**EC_{50}** (frond number)	0.0125	80	0.0168	1.34	yes
Amphibians	Acute – Rainbow	**LC_{50}**	0.22	15	0.0896	0.41	no
	Chronic – ELS	**NOEC** (body measurements and mortality)	0.0029	15	0.0896	30.9	yes

Sensitive Aquatic Organisms	Exposure Period	Description of Ecotox Endpoint	Ecotox Endpoint Value (mg a.i./L)	Water Depth (cm)	Refined Drift EEC (mg a.i./L)	Refined RQ	LOC exceeded
Marine Species							
Mysid shrimp	28-day chronic	**NOEC** (reproduction)	0.024	80	0.0168	0.7	no

Table 13 Refined Risk Assessment for Non-Target Aquatic Organisms Exposed to Metconazole Runoff

Organism	Exposure	Toxicity (mg a.i./L)	Runoff EEC (mg a.i./L)	RQ	LOC Exceeded
Daphnid	21-day chronic	NOEC (reproduction): 2.1	0.04	0.019	no
Rainbow trout	96-hour acute	LC_{50}: 0.22	0.04	0.18	no
	95-day ELS Chronic	NOEC (sublethal effects): 0. 009	0.04	4.44	yes
	95-day ELS Chronic	NOEC (body measurements and mortality): 0.0029	0.04	13.79	yes
Fathead Minnow FULL LIFE CYCLE (New Study)	Full life cycle – 180 days	NOEC (mortality, repro, growth and liver toxicity): 0.0032	0.04	12.5	yes
Green Algae	96-hour acute	EC_{50} (biomass and cell density): 0.1	0.04	0.4	no
Diatom	96-hour acute	EC_{50} (biomass and cell density): 0.0485	0.04	0.82	no
Aquatic Vascular Plant	7-day Acute	1/10 EC_{50} (frond number): 0.0125	0.04	3.2	yes

Organism	Exposure	Toxicity (mg a.i./L)	Runoff EEC (mg a.i./L)	RQ	LOC Exceeded
Amphibians	96-hour Acute	1/10 LC_{50} (surrogate fish data):0.022	0.079	3.59	yes
	95-day ELS Chronic	NOEC(surrogate fish data): 0.0029	0.057	19.66	yes
Mysid shrimp	28-day chronic	NOEC (reproduction): 0.024	0.04	1.67	yes

Table 14 Registered alternative products for turf diseases registered on the Tourney Fungicide label

Disease	Alternative active ingredients
Dollar spot (*Sclerotinia homeocarpa*)	thiophanate-methyl (1) iprodione (2) propiconazole (3) myclobutanil (3) boscalid (7) penthiopyrad (7) fluoxastrobin (11) pyraclostrobin (11) chlorothalonil (M) *Bacillus subtilis* strain QST 713 (44) mineral oil (NC)
Anthracnose foliar blight (*Colletotrichum cereale*)	propiconazole (3) penthiopyrad (7) azoxystrobin (11) trifloxystrobin (11) fosetyl-AL (33) chlorothalonil (M) *Bacillus subtilis* strain QST 713 (44)
Anthracnose basal rot (*Colletotrichum cereale*)	trifloxystrobin (11) fosetyl-AL (33)

Disease	Alternative active ingredients
Brown patch (*Rhizoctonia solani*)	thiophanate-methyl (1) iprodione (2) propiconazole (3) myclobutanil (3) penthiopyrad (7) azoxystrobin (11) pyraclostrobin (11) trifloxystrobin (11) captan (M) chlorothalonil (M) *Bacillus subtilis* strain QST 713 (44)
Pink snow mould (*Microdochium nivale*)	thiophanate-methyl (1) iprodione (2) propiconazole (3) triticonazole (3) carbathiin + oxycarboxin + thiram (7 + M) azoxystrobin (11) pyraclostrobin (11) trifloxystrobin (11) chlorothalonil (M) mineral oil (NC)
Grey snow mould (*Typhula incarnata, T. ishikariensis*)	thiophanate-methyl (1) iprodione (2) propiconazole (3) triticonazole (3) myclobutanil (3) carbathiin + oxycarboxin + thiram (7 + M) azoxystrobin (11) pyraclostrobin (11) trifloxystrobin (11) chlorothalonil (M) mineral oil (NC) *Typhula phacorrhiza* strain 94671 (NC)
Waitea patch (*Waitea circinata*)	propiconazole (3) azoxystrobin (11)

Table 15 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed label claim	Supported / Unsupported
Control of anthracnose basal rot and anthracnose foliar blight (*Colletotrichum cereale*) on turfgrass at a rate of 8.4 g/100 m^2 applied on a 14 day interval.	Supported for one application.
Control of brown patch (*Rhizoctonia solani*) on turfgrass applied at 8.4–11.2 g/100 m^2 on a 14 day interval.	Supported for one application.
Control of dollar spot (*Sclerotinia homoeocarpa*) on turfgrass applied at 8.4–11.2 g/100 m^2 on a 14 to 21 day interval or at 11.2 g/100 m^2 on a 28 day interval.	Supported for one application at 8.4–11.2 g/100 m^2.
Control of grey snow mould (*Typhula ishikariensis, T. incarnata)* on turfgrass applied once prior to permanent snow cover at 44.8 g/100 m^2 or at 11.2–13.4 g/100 m^2 tank mixed with 250 g a.i. of chlorothalonil.	Supported at 11.2 g/100 m^2 as a tank mix with chlorothalonil. The trade names Daconil 2787 Flowable Fungicide and Daconil Ultrex Fungicide will appear on the label as possible chlorothalonil tank mix partners.
Control of pink snow mould (*Microdochium nivale)* on turfgrass applied once prior to permanent snow cover at 44.8 g/100 m^2 or at 11.2–13.4 g/100 m^2 tank mixed with 250 g a.i. of chlorothalonil.	Supported at 11.2 g/100 m^2 as a tank mix with chlorothalonil (Daconil 2787 Flowable Fungicide or Daconil Ultrex Fungicide).
Control of summer patch (*Magnaporthe poae*) on turfgrass at a rate of 11.2 g/100 m^2 on a 14 day interval.	Supported for one application.
Control of waitea patch (*Waitea circinata*) on turfgrass at a rate of 13.8 g/100 m^2 on a 14 day interval.	Supported for one application at 11.2 g/100 m^2.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Table 1 Differences Between MRLs in Canada and in Other Jurisdictions

Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for metconazole.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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1926045	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Composition, Starting Materials, Description of the Production Process, and Discussion of the Formation of Impurities Alternate Manufacturing Site, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, CBI
1926046	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Composition, Starting Materials, Description of the Production Process, and Discussion of the Formation of Impurities Alternate Manufacturing Site, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, CBI
1926040	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Preliminary Analysis, Certified limits, and Enforcement Analytical Method - Alternate Manufacturing Site, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4
1926041	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Preliminary Analysis, Certified limits, and Enforcement Analytical Method - Alternate Manufacturing Site, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1926042	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Preliminary Analysis, Certified limits, and Enforcement Analytical Method - Alternate Manufacturing Site, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1926044	2009, Metconazole Fungicide Technical (KNF-S-474m): Product Chemistry Group A - Preliminary Analysis, Certified limits, and Enforcement Analytical Method - Alternate Manufacturing Site, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2016923	2.13.3_Manufacturing dates of batches of MCZ technical, DACO: 2.13.3 CBI
1924255	2006, Product Identity and Composition of Metconazole 50 WDG; Description of Materials Used to Produce the Product Metconazole 50 WDG; Description of the Production Process for Metconazole 50 WDG; Description of the Formulation Process for Metconazole 50 WDG, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1, CBI
1924258	2006, Product Identity and Composition of Metconazole 50 WDG; Description of Materials Used to Produce the Product Metconazole 50 WDG; Description of the Production Process for Metconazole 50 WDG; Description of the Formulation Process for Metconazole 50 WDG; Discussion of Formation of Impurities for Metconazole 50 WDG, Preliminary Analysis of Metconazole 50 WDG, Preliminary Analysis of Metconazole 50 WDG, Certified Limits for Metconazole 50 WDG, Enforcement Analytical Method for Metconazole 5 WDG, Submittal of Samples for Metconazole 50 WDG, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1
1924265	2007, Storage Stability and Corrosion Characteristics of Metconazole 50 WDG, DACO: 3.5.10,3.5.14
1924269	2010, Storage Stability and Corrosion Characteristics of Metconazole 50 WDG (VC-1585 Formulation), DACO: 3.5.10,3.5.14

1924260	2009, Physical and Chemical Properties for Metconazole 50 WDG Fungicide: Colour, Odour, Formulation Type, and Container Material and Description, DACO: 3.5.1, 3.5.3, 3.5.4, 3.5.5
1924274	2006, Physical and Chemical Properties of Metconazole 50 WDG, DACO: 3.5.2, 3.5.6, 3.5.7, 3.5.8
1924262	2009, Waiver for the requirement of Viscosity, Flammability, Miscibility, Explodability & Dielectric Breakdown Study for Metconazole 50 WDG Fungicide, DACO: 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.9
1924265	2007, Storage Stability and Corrosion Characteristics of Metconazole 50 WDG, DACO: 3.5.10,3.5.14
1924269	2010, Storage Stability and Corrosion Characteristics of Metconazole 50 WDG (VC-1585 Formulation), DACO: 3.5.10,3.5.14

2.0 Human and Animal Health

PMRA Document Number	Reference
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1926048	2010, Immunotoxicity Study in Male Wistar Rats: Administration via the Diet for 4 Weeks, DACO: 4.8(B)
2191625	2012, A Dermal Prenatal Developmental Toxicity Study of Metconazole in Rabbits, DACO: 4.5.3
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2220338	2012, APPENDIX B Metconazole: Mouse (91-Week) Oncogenicity Study: Weekly Clinical Observations Data, DACO: 4.4.3
2220339	2012, MS Excel Spreadsheet - Data Summary of Metconazole Mouse Oncogenicity Study Weekly Clinical Observations, DACO: 4.4.3
1563654 and 1563664	1999, Exposure of Professional Lawn Care Workers During The Mixing and Loading of Dry and Liquid Formulations and the Liquid Application of Turf Pesticides Utilizing A Surrogate Compound, Study Number OMA002, ORETF, DACO: 5.3, 5.4
1924323	2010, Use Description and Scenario (Mixer/Loader/Applicator and Post-application) for Metconazole 50 WDG Fungicide and Tourney Fungicide, DACO: 5.2
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1924248	2006, Data Evaluation Record on Transferable turf on Metconazole Turfgrass, DACO: 12.5.5
2115788	2008, Agricultural Re-entry Task Force (ARTF), Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients, DACO: Memo

3.0 Environment

PMRA Document Number	Reference
2050955	2002, Metconazole (BAS 555 F): Degradation in Soil Under Aerobic Conditions, DACO: 8.2.3.4.2
2050953	2002, Metconazole (BAS 555 F): Rate of Degradation in Soil Under Aerobic Conditions at 10°C, DACO: 8.2.3.4.2
1923906	2006, Terrestrial Field Soil Dissipation of Metconazole in Ontario, Canada, DACO: 8.3.2.1
1923705	2010, Terrestrial Field Soil Dissipation of Metconazole on Bare Soil in Saskatchewan, DACO: 8.3.2.1
1924348	2010, Terrestrial Field Soil Dissipation of Metconazole on Established Turfgrass in Nova Scotia, DACO: 8.3.2.1
1924351	2010, Terrestrial Field Soil Dissipation of Metconazole on Established Turfgrass in Nova Scotia, DACO: 8.3.2.1
1924353	2009, Terrestrial Field Soil Dissipation of Metconazole on Established Turfgrass in Oregon, DACO: 8.3.2.2
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1950178	BASF 555 F (Metconazole) – Life Cycle Toxicity Test on the fathead minnow (*Pimephales promelas*) in a flow-through system, DACO: 9.5.3.2

4.0 Value

PMRA Document Number	Reference
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